

510(k) Summary**Date: 3/31/2010****Submitter Name and Address**

CardioNet, Inc.
1010 2nd Avenue, Suite 700
San Diego, CA 92101

APR - 8 2010

Contact Person:

Kent Saylor
619-243-7560

1. Name of Device

Trade/Proprietary Name: Model CN1006 - CardioNet ECG Monitor with Arrhythmia Detection

Common/Usual Name: Arrhythmia detector and alarm

Classification Name: CFR §870.1025 Product code DSI 'Arrhythmia Detector and Alarm'

Class: Class II, Special Controls

2. Predicate Devices

The predicate devices selected are as follows:

1. **CardioNet Ambulatory ECG Monitor with Arrhythmia Detection** manufactured by CardioNet, Inc. cleared by FDA under 510(k) number K053263 on April 25, 2006.
2. **CardioNet Ambulatory ECG Monitor with Arrhythmia Detection** manufactured by CardioNet, Inc. cleared by FDA under 510(k) number K063222 on November 14, 2006.
3. **CG6108 – ACT-3L Continuous ECG Monitor and Arrhythmia Detector** manufactured by Card Guard Scientific Survival Ltd., cleared by FDA under 510(k) number K081257 on May 29, 2008.

3. Device Description

The CardioNet ECG Monitor with Arrhythmia Detection CN1006 is an ambulatory ECG monitor with capability to detect cardiac arrhythmias and transmit ECG data to a CardioNet staffed monitoring center.

The subject device is comprised of three (3) main components: 1) a patient-worn Sensor, 2) a Monitor and 3) a charging Base.

A Sensor acquires the ECG signal from the patient's body and transmits the signal to PDA sized monitor where the data is stored and analyzed by an automated arrhythmia analysis algorithm residing in the Monitor. When events are detected by the analysis algorithm or when indicated by the patient pressing

the event key on the Monitor, the Monitor will transmit the data to the Monitoring Center. Data can be uploaded to the Monitoring Center in a variety of ways - Transmitted via Cellular RF modem or via RF to the Base for transmission via the patient's landline telephone. The data is received and reviewed by trained technicians using the Monitoring Services Application.

4. Indications for Use and Contraindications

The indications for use for the subject device are as follows:

1. Patients who have a demonstrated need for cardiac Monitoring. These may include but are not limited to patients who require Monitoring for: a) non-life threatening arrhythmias such as supraventricular tachycardias (e.g. atrial fibrillation, atrial flutter, PACs, PSVT) and ventricular ectopy; b) evaluation of bradyarrhythmias and intermittent bundle branch block, including after cardiovascular surgery and myocardial infarction; and c) arrhythmias associated with co-morbid conditions such as hyperthyroidism or chronic lung disease.
2. Patients with symptoms that may be due to cardiac arrhythmias. These may include but are not limited to symptoms such as: a) dizziness or lightheadedness; b) syncope of unknown etiology in which arrhythmias are suspected or need to be excluded; c) dyspnea (shortness of breath).
3. Patients with palpitations with or without known arrhythmias to obtain correlation of rhythm with symptoms.
4. Patients who require outpatient monitoring of antiarrhythmic therapy: a) Monitoring of therapeutic and potential proarrhythmic effects of membrane active drugs, b) Monitoring of effect of drugs to control ventricular rate in various atrial arrhythmias (e.g. atrial fibrillation).
5. Patients recovering from cardiac surgery who are indicated for outpatient arrhythmia Monitoring
6. Patients with diagnosed sleep disordered breathing including sleep apnea (obstructive, central) to evaluate possible nocturnal arrhythmias
7. Patients requiring arrhythmia evaluation of etiology of stroke or transient cerebral ischemia, possibly secondary to atrial fibrillation or atrial flutter.
8. Patients requiring measurement, analysis and reporting of QT interval, excluding patients with a documented history of sustained atrial fibrillation or atrial flutter
9. Patients who require monitoring for potential arrhythmias based on risk factors (e.g. atrial fibrillation).
10. Patients requiring measurement of ST segment changes. The device is not intended to sound any alarms for ST segment changes.

Contraindications:

1. Patients with potentially life-threatening arrhythmias who require inpatient Monitoring.
2. Patients who the attending physician recommends should be hospitalized for ECG monitoring.
3. This device should not be used for monitoring of QT interval during the initiation of antiarrhythmic therapy, where in-hospital monitoring is required by the labeling of that drug.
4. The device does not replace the QT interval measurement by a trained observer using diagnostic 12 lead ECG in a clinical environment. This device is not intended to sound any alarms for QT interval changes.
5. The device does not annotate QT interval for QRS durations >160 ms or for T wave amplitudes $\leq 5\%$ of the peak QRS amplitude.

5. Comparison to predicate devices

The table below compares the features between the subject device and predicate devices.

Predicate Device Feature Comparison Table

Feature being compared	Subject Device	Predicate Device
ECG algorithm	Model CN1006 (K093288)	CardioNet Model CN1003 (K053263)
QT Interval Measurement	Model CN1006 (K093288)	CardioNet Model CN1004 (K063222)
ST Segment Measurement	Model CN1006 (K093288)	Card Guard CG6108-ACT3L (K081257)

6. Performance Test Summary

The subject device meets the requirements of the following performance standards in accordance with Class II Special Controls Guidance document: Arrhythmia Detector and Alarm

- AAMI/ANSI EC 57 1998/(R) 2003 – Testing and Reporting Performance Results of Cardiac Rhythm and ST Segment Measurement Algorithms
- AAMI EC 53/(R) 2001 ECG Cables and leadwires
- International Electrotechnical Commission (IEC) 60601-1:1988 +A1:1991 +A2:1995 Medical Electrical Equipment - Part 1: General Requirements for Safety
- IEC 60601-1-2, Medical Electrical Equipment - Part 1-2: General Requirements for Safety - Collateral standard: Electromagnetic Compatibility - Requirements and Tests (Edition 2:2001)
- AAMI / ANSI EC38:2007, Medical electrical equipment - Part 2-47:

Particular requirements for the safety, including essential performance, of ambulatory electrocardiographic systems. (Cardiovascular)

- AAMI / ANSI / ISO 10993-1:2003, Biological evaluation of medical devices -- Part 1: Evaluation and testing. (Biocompatibility)

7. Substantial Equivalence Conclusion

CardioNet ECG Monitor with Arrhythmia Detection, Model CN1006 is safe, effective, and substantially equivalent to the predicate devices as supported by the descriptive information and the performance testing.



Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room W-066-0609
Silver Spring, MD 20993-0002

APR - 8 2010

CardioNet, Inc.
c/o Mr. Kent Sayler
Director RA/QA
1010 2nd Avenue, Suite 700
San Diego, CA 92101

Re: K093288
Device Name: Ambulatory ECG Monitor with Arrhythmia Detection Model # CN1006
Regulation Number: 21 CFR 870.1025
Regulation Name: Arrhythmia Detector and Alarm
Regulatory Class: Class II (Two)
Product Code: DSI
Dated: April 1, 2010
Received: April 6, 2010

Dear Mr. Sayler:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

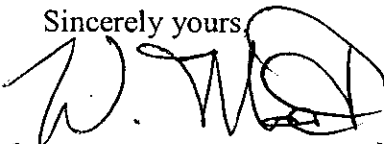
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to <http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucml15809.htm> for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to <http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm> for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address <http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>.

Sincerely yours,



For Bram D. Zuckerman, M.D.

Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K093288

Device Name: CardioNet Ambulatory ECG Monitor with Arrhythmia Detection

Indications for Use:

The CardioNet Ambulatory ECG Monitor with Arrhythmia Detection intended use is for:

1. Patients who have a demonstrated need for cardiac Monitoring. These may include but are not limited to patients who require Monitoring for: a) non-life threatening arrhythmias such as supraventricular tachycardias (e.g. atrial fibrillation, atrial flutter, PACs, PSVT) and ventricular ectopy; b) evaluation of bradyarrhythmias and intermittent bundle branch block, including after cardiovascular surgery and myocardial infarction; and c) arrhythmias associated with co-morbid conditions such as hyperthyroidism or chronic lung disease.
2. Patients with symptoms that may be due to cardiac arrhythmias. These may include but are not limited to symptoms such as: a) dizziness or lightheadedness; b) syncope of unknown etiology in which arrhythmias are suspected or need to be excluded; c) dyspnea (shortness of breath).
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4. Patients who require outpatient monitoring of antiarrhythmic therapy: a) Monitoring of therapeutic and potential proarrhythmic effects of membrane active drugs, b) Monitoring of effect of drugs to control ventricular rate in various atrial arrhythmias (e.g. atrial fibrillation).
5. Patients recovering from cardiac surgery who are indicated for outpatient arrhythmia Monitoring.

Prescription Use X
(Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use _____
(21 CFR 801 Subpart C)

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6. Patients with diagnosed sleep disordered breathing including sleep apnea (obstructive, central) to evaluate possible nocturnal arrhythmias
7. Patients requiring arrhythmia evaluation of etiology of stroke or transient cerebral ischemia, possibly secondary to atrial fibrillation or atrial flutter.
8. Patients requiring measurement, analysis and reporting of QT interval, excluding patients with a documented history of sustained atrial fibrillation or atrial flutter
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Contraindications:

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5. The device does not annotate QT interval for QRS durations >160 ms or for T wave amplitudes $\leq 5\%$ of the peak QRS amplitude.

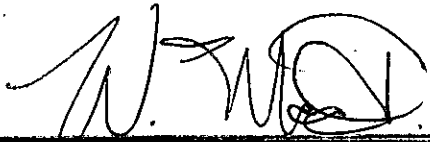
Prescription Use X
(Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use _____
(21 CFR 801 Subpart C)

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Concurrence of CDRH, Office of Device Evaluation (ODE)



(Division Sign-Off)
Division of Cardiovascular Devices

510(k) Number K093889/500